UDI in the European MDR proposal

Spots as excerpts of the MDR proposal 2017-02-22 in comparison with the FDA UDI regulations

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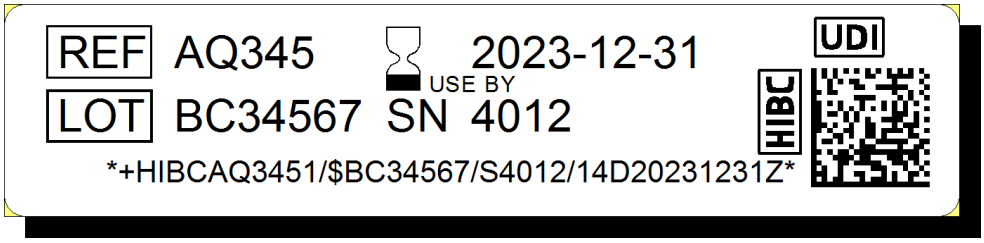

Figure 1: Sample UDI package label

1 Introduction

The UDI system consists of a public data base and product marking of “the UDI” by a code symbol(s) and the human readable interpretation. An example label is shown in figure 1.

The Proposal of the European Union [1] for the new regulation for medical devices (MDR) is available. It includes the UDI system under Article 27 "UDI System" and in its corresponding Annex VI.
The current text is available as translations to all official EU languages. It is very likely that this text will be published in may 2017, becoming a binding law for all 28 member states but it is not guaranteed yet, that no further modification will be done. Other countries like Switzerland may also adopt this text with little modification.
This paper gives an informal overview as excerpts of the UDI relevant parts of the EU regulation compared with the FDA UDI regulation [2]. The frame for both is relevant final UDI document released by the IMDRF [3].
The aim of this paper is to assist manufacturers, resellers and users to implement UDI.
The binding text will be the one finally published by the EC.

2 Document history

2016-07-27: First public released.

2016-09-23: Modified due dates to supposed publication date of march 2017.
Added library reference [5] for placement of non-UDI fields.

2017-01-17: Added IVD due dates.

2017-04-04: Adopted to new draft. The UDI part is not much modified, but the numbering has changed due to huge changes in other parts.

2017-04-19: Adopted supposed publishing date due to positive vote.

3 Due dates for Europe

The following due dates will be effective for Europe under the premise that the regulation gets into force in August 2017. The general application is in August 2020 including the UDI Data Base registration. There are delayed due dates for product marking depending on the device class and type. The following table resumes the resulting due dates:

	2021	2022	2023	2024	2025	2026	2027
Class III[1] and Implants	Package Labeling		Device Marking				
Class IIa and IIb			Package Labelling		Device Marking		
Class I					Package Labelling		Device Marking
Data Base (all classes)	Accessable: 1.5 years after application + when audit passed. Mandatory 1.5 years later.						

The data base due date is specified as 1.5 years after application plus an eventual delay due to data base organisation and the conformity audit.

1) European Union medical device risk class (I, IIa, IIb, III) may be different to FDA US class (I, II, III, unclassified) for the same product.

The due-dates for IVD are roughly 2 years later:

	2023	2024	2025	2026	2027
Class D	Package Labeling				
Class C and B			Package Labelling		
Class A					Package Labelling
Data Base (all classes)	1.5 years after application + 'X'				

4 Package marking

4.1 Which packing level has to bear UDI

The UDI shall be presented on the unit of use package and all higher package levels in form of a Code and in text (HRI: human readable interpretation).

There are a set of additional regulations and exemptions to this general rule:

- shipping containers are exempted (like US)
- Unit of Use level marking is exempted if there are space constraints and a higher level of packaging with an UDI is always present. (US: no exemption)
- Class I and IIa single use devices are exempted if there is a higher level of packaging with an UDI present at usage (dispenser box). (US: OK for all classes)
- In case of space constraints, the HRI may be omitted. For Home Care, the HRI is mandatory and the code may be omitted in this case. (US: No exemption)
- A code of a lower package configuration may be made visible through a hole/window in the packaging to avoid to mark the higher level. (US: not defined, but ok)
- Configurable devices (ex.: EEG system with custom cable together) may have a single UDI for all configurations. The distinct configuration is identified by the UDI-PI (Serial/Lot number) (US: not allowed).
- Systems and procedure packs bear an UDI on the package. The UDI rules are similar to US convenience kits, e.g. single use components don't need an individual UDI.

4.2 UDI-PI fields

The fields contained in the UDI-PI may be regulated by device class rules.
There are additional rules:

- A manufacturing date presented on the packing is optional in the UDI-PI if there is an exiration date contained. (US: No exemption)
- Other non UDI-fields are allowed within the code. Apparently, there is no constraint, that they have to be added after the UDI (US: Additional non-UDI data elements shall be placed at the end of the code [5]).

4.3 Other labeling requirements

In addition to UDI, the following labeling rules are included:

- If the manufacturer is outside the EU, an authorized representative must be mentioned on the packaging (US: not necessary for the US)
- Expiration date may omit the day in text and code (US requires text format YYYY-MM-DD, but code may omit the day where last day of the month is valid)
- A manufacturing date must be clearly identifyable as a clear text field or as a part of the serial or lot number, if the product package does not contain an expiration date. (US: not required)

5 Device marking

Reusable devices must be directly marked with code and HRI if possible. (US: Code or text are accepted as well.)

6 UDI Data base access

The UDI Data Base is a module of Eudamed (**Eu**ropean **Da**tabank on **Me**dical **D**evices).
The public access is free of charge also up- and download should be possible automatically .
The manufacturers pass the master data directly to Eudamed.
There is a product change notification time limit of 3 months for the manufacturers (US: No designated notification time).
The data base entry is a pre-requisite to put medical devices in the market (like US).UDI Data Base fields
The field set and field format is not described for the EU Data Base in detail yet. The following differences may be observed in comparison with The GUDID of the FDA:

- The Nomenclature is not jet fixed. It is only claimed to be recognized on an international level and free of charge. Following rumors, an FDA-like model with GMDN is in vue. (US: GMDN or compatible FDA PTs)
- The virtual DI for unlabeled medical devices “Unit of Use DI” is provided (like in the FDA GUDID).
- A possibility to specify the number of reuses is provided (US: not possible).
- Possibility to add a URL for additional information, instruction of use, etc. via Internet. This field was proposed by IMDRF. (US: There is no field for it in the FDA GUDID.)

7 Where to document the UDI

The UDI shall be used:

- The Base UDI-DI (e.g. only lowest packing level) shall be mentioned on the declaration of conformity for each product.
- The relevant UDI shall be add to incidents reports and safety corrections
- The UDI of class III implantable device shell be documented and stored by all parties in the supply chain, like resellers, hospitals, doctors, etc.. This requirement may be extended to other medical device classes by the national bodies.

8 Quality control for UDI symbols

The EU document requires a control of the UDI-Code within the quality management system.
This is also required by the extension “Labeling and Packaging Control” of the FDA Quality rules for medical device manufacturing [4].

9 References

[1] Concil of the European Union: "Position of the Council at first reading with a view to the adoption of a Regulation of the European Parliament and of the council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC", 2017-02-22
http://data.consilium.europa.eu/doc/document/ST-10728-2016-INIT/en/pdf

[2] FDA: "Final Rule - Unique Device Identification System", 2013-09-24
https://www.federalregister.gov/articles/2013/09/24/2013-23059/unique-device-identification-system

[3] IMDRF: "UDI Guidance - Unique Device Identification (UDI) of Medical Devices", IMDRF UDI Working Group, 2013-12-09
http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance-140901.pdf

[4] FDA: “QUALITY SYSTEM REGULATION, Subpart K—Labeling and Packaging Control”, CFR.I.H.820, 2016-07-18
http://www.ecfr.gov/cgi-bin/text-idx?SID=5fc73198ff18195830b906b039e9b954&mc=true&node=pt21.8.820&rgn=div5#se21.8.820_1120

[5] FDA: “Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI)”, Draft Guidance, 2016-07-26
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM512648.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery